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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/549,342 | 04/13/2000 | Tracey L. Colpitts | 5972.US.P6 | 7494 |

23492 7590 04/22/2002

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| EXAMINER |
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HARRIS, ALANA M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1642

DATE MAILED: 04/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/549,342

Applicant(s)

COLPITTS ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 39 and 41-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 39 and 41-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Claims 1-6, 39 and 40-47 are pending.
Claims 7 and 40 have been cancelled.
Claims 1-6, 39 and 41-47 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

3. Applicants submitted an amendment (Paper number 11, received January 23, 2002) to the specification now reflecting the proper continuing data for the first line of the specification. However, the declaration continues to reference U.S. serial number 08/215,818 in the continuing data. As stated in the first action on the merits (Paper number 10, mailed September 17, 2001) this number should be 09/215,818.

Drawings

4. The drawings submitted February 26, 2002 as Paper number 12 have been approved by the draftsman.

Withdrawn Objections

Claim Objections

5. Claim 5 is no longer because it contains reference to an amino acid residue with its respective identifying sequence identification number.

6. Claims 7 and 40 are no longer objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim due to the cancellation of the claims.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

7. The rejection of claims 41-47 under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement commensurate with the scope of the claimed invention is withdrawn in light of the cancellation of claims 7 and 40.

8. The rejection of claims 41-47 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a multimeric polypeptide (MPA) consisting of EU250 (SEQ ID NO:3), BU101 (SEQ ID NO:2) and TU104 (SEQ ID NO:10) does not reasonably provide enablement for a MPA consisting of arbitrary fragments of the said sequences is withdrawn in light of claim amendments. Claims 7 and 40 have been cancelled.

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9. The rejection of claims 1-6, 39 and 41-47 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants' arguments. Claims 7 and 40 have been cancelled.

Claim Rejections - 35 USC § 103

10. The rejection of claims 1-6, 39 and 41-47 under 35 U.S.C. 103(a) as being unpatentable over by U.S. Patent number 6,066,724 (filed March 21, 1997) is maintained. Claims 7 and 40 have been cancelled.

Applicants submit that U.S. Patent #6,066,724 (Ni et al.) teaches hESF I, II and III polypeptides, however they argue that "[t]here is absolutely no teaching or suggestion in the patent as to which of the polypeptides should be used in combination. Applicants further assert that there is no teaching or suggestion that the sequence (hESF II) corresponding to EU250 of the claimed invention must be present in a multimeric polypeptide complex and furthermore the TU104 sequence is only 92.4% similar to the sequence (hESF III) of the said patent. This is found unpersuasive.

As set forth in the first action on the merits (Paper number 10, mailed September 17, 2001) Applicants' claimed sequences, SEQ ID NO: 2 (BU101) and 3 (EU250) are 100% homologous to Patent '724 sequences hESF II and III, respectively. Column 16, lines 21-24 clearly states that the said sequences, as well as hESF I, which is 92.4% homologous to Applicants' SEQ ID NO: 10 (TU104) is comprised within a larger polypeptide. The patent teaches the combination of the sequences, as well as

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polyclonal or monoclonal antibodies produced by the use of the said polypeptide sequences. For the reasons expressed in the preceding sentences and in Paper #10 the 103(a) is maintained.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.
April 11, 2002



ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600